

## EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

☐ Repeal    ☒ Modification

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2. Administrative Rule Chapter, Title and Number

ATCP 75, Retail Food Establishments, and ATCP 75 Appendix, The Wisconsin Food Code

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3. Date Rule promulgated and/or revised; Date of most recent Evaluation

Recent corrections made in 2016

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4. Plain Language Analysis of the Rule, its Impact on the Policy Problem that Justified its Creation and Changes in Technology, Economic Conditions or Other Factors Since Promulgation that alter the need for or effectiveness of the Rule.

The Department is updating ch. ATCP 75 by incorporating large parts of repealed ch. DHS 196 (Restaurants) and repealing rules in ch. ATCP 75 dealing with agent programs. These agent program rules are now found in the new ch. ATCP 74 (Local Agents and Regulation) which also incorporates rules from the repealed ch. DHS 193.

With the transfer of the Food Safety and Recreational Licensing section from Department of Health Services to the Department, changes were made to merge the rules used by the two agencies. In addition to new language clarifying the responsibilities of food retailers who take advantage of the exemption from the requirement to hold a food processing plant license under ch. ATCP 70 but wholesale up to 25% of their gross food sales, the proposed ch. ATCP 75 will incorporate, for the first time, specific definitions for “wholesaling” and “retailing” that are now being incorporated into chs. ATCP 70 and ATCP 55 to provide guidance, clarity, and uniformity for food processors and retailers in Wisconsin.

The proposed ATCP 75 contains language that specifically clarifies the responsibilities for retail food establishments exempt from the requirement to hold a food processing plant license but also doing a limited amount of wholesaling, and ensures that these establishments follow the ATCP 70 safety, processing, and labeling requirements for the food produced for wholesaling. This not only ensures all persons doing similar business activities are similarly regulated, but also ensures that all businesses selling at remote locations have the enhanced food safety processes in place (such as a written recall plan and a written food safety production plan), as required by rules in ch. ATCP 70.

A major change in this rule is the elimination of the exemption from the requirement to hold a retail food establishment license for persons holding either a meat establishment license issued by the Department or a grant of meat/poultry inspection from the federal government. Prior to the adoption of this rule, those meat establishments were allowed to retail up to 25% of total meat sales without a retail food establishment license because of the pervasive state or federal inspection of meat processing. However, recent discussions between the regulators in food and meat inspection have made it clear that meat and poultry products sold at retail, but not marked with the state or federal mark of inspection, as well as other aspects of a retail food establishment, were not being inspected by meat inspection staff. The result of this oversight is that those establishments with meat establishment licenses or federal grants of inspection would not be able to retail any product other than meat or poultry products bearing the legend. With the proposed rule, the department would make it possible for them to continue to sell a full line of products while assuring the consuming public that the food products were subject to a proper inspection. It also levels the playing field for businesses already licensed to produce meat and poultry products only for retail sale.

The Department worked to combine the duties, activities, and expectations of both the merged agencies in a way that eliminates duplication, clarifies expectations, and, to the extent possible, ensures that multiple licenses are not needed. The Department has, however, balanced these objectives with its responsibility to the public and its mission as food safety regulators to see that all food is produced according to law and under some form of inspection. In some cases, such as meat establishments that produce some products under state or federal inspection with a mark of inspection and some product without that inspection or mark, the proposed rule will allow an additional retail license from the state or

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local agency with jurisdiction in that area, as well as the state meat establishment license or the federal grant of inspection.

The new rule focuses on defining and clarifying the rules for micro-markets, vending machines, and the commissaries that serve both of those business types. The commissaries for both micro-markets and vending machines are now to be licensed as food processing plants, which reflects the operations of these commissaries. In addition, micro-markets are defined to reflect that they operate without a person in charge at all times in overseeing their operations, which is a requirement for other types of retail food establishments.

Greater clarification is also given to the Department's rules for Hazard Analysis Critical Control Point ("HACCP") Plans and HACCP variances, including the procedure for variance applications. New language also simplifies the protocols establishments must follow for doing vacuum packing and sous-vide processing.

A significant change in the Wisconsin Food Code deals with cheese curds. The Department proposes to include language that references a process authority study on cheese curds, which validates the 24-hour at-room temperature rule and, moreover, allows the Department to meet Standard 1 of the FDA's Retail Food Regulatory Standards Program.

This proposed rule harmonizes the different licensing rules that had been used by DHS and the Department, for mobile retail food establishment bases. Those different rules had created a licensing inequity between those operations, depending on the overseeing agency. These inconsistencies have now been eliminated, and the proposed rule also clarifies the rules for using those bases.

The Department renumbered and consolidated many provisions in the Wisconsin Food Code to achieve greater ease in use and to allow for the incorporation of rules related to micro-markets and vending machines. The Department has also revisited the criteria for licensing fees, changing from income-and-sales-volume-based fees to risk-complexity-based fees.

Other clarifications, changes, and additions include the following:

- Language and terminology are standardized and clarified between the two merged programs.
- The definitions section is expanded to facilitate understanding of the merged language and the new programs.
- The Wisconsin Food Code is rearranged to help clarify its contents and applications. It is also expanded to stay current with recent federal and state initiatives.

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#### 5. Describe the Rule's Enforcement Provisions and Mechanisms

The Department has broad general authority, pursuant to s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. The Department also has general authority, pursuant to s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The Department has specific authority, pursuant to s. 97.30 (5), Stats., to adopt rules dealing with fees; setting facility construction and maintenance standards; setting rules for the design, installation, maintenance, and cleaning of equipment and utensils; personnel standards; food handling and storage; sanitary production and processing of food; food sources; and food labeling.

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#### 6. Repealing or Modifying the Rule Will Impact the Following (Check All That Apply)

- ☐ State's Economy  
☒ Local Government Units

- ☒ Specific Businesses/Sectors  
☐ Public Utility Rate Payers  
☒ Small Businesses

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#### 7. Summary of the Impacts, including Compliance Costs, identifying any Unnecessary Burdens the Rule places on the ability of Small Business to conduct their Affairs.

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The rule is expected to have minimal economic effect, as noted below.

#### **Businesses and Business Sectors:**

Under the rule, new mobile restaurants (i.e. food carts) will need an additional license for their restaurant “base.” For those retail food establishments requiring a licensed base, already-licensed mobile restaurants will see no change in requirements because their bases were licensed under the DHS rules that were transferred to the department. Mobile retail food establishments that operate at special events or temporary events will not need this license, just as mobile restaurants operating at temporary events, such as farmers’ markets, currently do not need it. Facilities already licensed as mobile restaurants will not be affected because their bases have the requisite license under prior rules of DHS. Mobile retail food establishments that operate at special events or temporary events and mobile restaurants operating at temporary events such as farmers’ markets will not need the new base license .

For those operators with a base serving mobile retail food establishments that only sell non-perishable packaged foods, the effect will also be minimal. The only operators who may face increased regulatory requirements, and the associated expenses to meet them, are those operators who are also doing complex processing and preparation of potentially hazardous food. Some activities performed in those settings must also be done under the HACCP system, such as fish processing that would require implementation of a Seafood HACCP system (as required in 21 CFR part 123, as cited in s. ATCP 70.18), juice processing that would require implementation of a Juice HACCP system (as required in 21 CFR part 120, as cited in s. ATCP 70.23), or the processing and/or repacking of marine shellfish that would require compliance with the HACCP-based Marine Shellfish Program found in s. ATCP 70.21.

The major change in ch. ATCP 75 is the change in the criteria for assigning license fees. The rule more realistically ties the cost of the license to the complexity and food safety hazards of the processing activities going on and not to the size of the establishment and dollar volume of sales. In many cases, larger establishments that may have been paying a higher license fee because of the sales volume will now pay a lower fee if their processing is not complex or hazardous. The Department’s analyses suggest that the overall change in total license fees charged will be negligible. The proposed licensing fee criteria more fairly reflects the time and personnel costs to the Department for the inspection.

The additional retail license should not pose a major fiscal impact on plants operating under state or federal meat inspection programs. Both meat inspection programs require all inspected products to be produced under HACCP. The retail program will be willing to accept state or federal HACCP plans for cured or shelf-stable products, and already requires them under the retail program. If the proposed rule is not approved, it may not be possible for establishments operating under USDA or Wisconsin meat inspection programs to continue to operate unlicensed, uninspected retail outlets.

The proposed changes in criteria for license fees were tested by applying the criteria to businesses in a representative county and evaluating the license fee change to each retail food establishment in that county.

The additional retail license should not pose a major fiscal impact on plants operating under state or federal meat inspection programs. Both meat inspection programs require all inspected products to be produced under HACCP. The retail program will be willing to accept state or federal HACCP plans for cured or shelf-stable products, and already requires them under the retail program. If the proposed rule is not approved, it may not be possible for establishments operating under USDA or Wisconsin meat inspection programs to continue to operate unlicensed, uninspected retail outlets.

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### Local Governmental Units and Public Utility Rate Payers:

The rule may have an impact on local governmental units because it defines licensing categories that may or may not be used by local agent health programs. It takes this into account, and also gives a fiscal year to adjust budgeting strategies when new rules or policies will have an impact on these local agencies. Overall, this is an update of existing regulations.

### Fiscal Impact:

Because food processing plants are already regulated by DATCP, this rule will not have a significant fiscal impact on state government and DATCP will absorb any costs with current budget and staff. This rule may have minimal fiscal effect on local governments, but not on public utility rate payers, since the regulation of some retail food establishments occurs on a local level.

The Department anticipates a slight loss in retail food establishment licensing revenue (<5%) because of the revisions to the licensing category tables in the rule. However, it is possible that the loss in revenue would be balanced by potential revenue from new licensing of mobile restaurant bases and shifting many mobile restaurant bases and vending commissary licenses from agent programs to the Department. Some of those entities were operating as wholesalers and were not eligible for licensure by agent programs.

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#### 8. List of Small Businesses, Organizations and Members of the Public that commented on the Rule and its Enforcement and a Summary of their Comments.

No comments were received during the economic impact comment period held August 8 - September 7, 2017. However, feedback on the rule was solicited from members of the Food Safety Advisory Council (FSAC), a group comprised of business and local health department agent representatives.

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#### 9. Did the Agency consider any of the following Rule Modifications to reduce the Impact of the Rule on Small Businesses in lieu of repeal?

- ☒ Less Stringent Compliance or Reporting Requirements  
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting  
☐ Consolidation or Simplification of Reporting Requirements  
☐ Establishment of performance standards in lieu of Design or Operational Standards  
☐ Exemption of Small Businesses from some or all requirements  
☒ Other, describe: Licensing criteria: The rule more realistically ties the cost of the license to the complexity of the processing activities going on and the food safety risk of those activities. In some cases, larger establishments that may have been paying a higher license fee because of the sales volume will now have that fee reduced if their processing is not complex.

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#### 10. Fund Sources Affected

☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

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#### 11. Chapter 20, Stats. Appropriations Affected 20.115 (1)(gb)

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#### 12. Fiscal Effect of Repealing or Modifying the Rule

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> No Fiscal Effect         | <input type="checkbox"/> Increase Existing Revenues            | <input type="checkbox"/> Increase Costs                                 |
| <input checked="" type="checkbox"/> Indeterminate | <input checked="" type="checkbox"/> Decrease Existing Revenues | <input checked="" type="checkbox"/> Could Absorb Within Agency's Budget |
|   |  | <input type="checkbox"/> Decrease Cost                                  |

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#### 13. Summary of Costs and Benefits of Repealing or Modifying the Rule

This rule continues to ensure that Wisconsin's retail food establishments meet federal requirements by adopting the Food and Drug Administration (FDA) Food Code. Not implementing the rule would mean that Wisconsin retail food establishments would not meet FDA standards and would be doing some wholesaling in competition with Food Processing plants without adequate process controls or oversight. Some products in the retail meat industry would not even be regulated by anyone.

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#### 14. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

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☐ Yes ☒ No

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### 15. Long Range Implications of Repealing or Modifying the Rule

The rule will continue to facilitate the working relationship between the department, the FDA, and the food processing industry. Long range implications include the continued vigilance of promoting healthy business practices that help businesses to grow and that ensure food safety guidelines are met.

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### 16. Compare With Approaches Being Used by Federal Government

The FDA does not have a retail food inspection or regulation program. The FDA promulgates the Model Food Code which is presented as a guide that is used in formulating state regulations or adopted by state programs to promote a uniform level of food safety throughout the nation.

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### 17. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Surrounding states have adopted various versions of the FDA's Model Food Code.

IL: Retail food establishments in Illinois are licensed at the county or municipal level. Cook County does not have a separate category for mobile retail food establishment bases. Licensing fees for retail food establishments are based on whether the establishment has seats for customers and if not, the total area occupied by the business. Chicago differentiates licenses for mobile food dispensers and mobile food preparers.

MN: Minnesota has different license categories for mobile and stationary retail food businesses, with the fee based on sales volume. There is no separate Minnesota license category for mobile retail food establishment bases. Retail food establishments (not restaurants) in Minnesota are primarily regulated by the Department of Agriculture. Minnesota restaurants are primarily regulated by county or municipal agencies. Hennepin County, for example, sets license fees based on menu breadth, degree of hazard of menu items, and size of operation, with separate categories for mobile and itinerant businesses.

IA: Iowa has a separate license category for a commissary serving a mobile retail food establishment. The retail food establishment category in Iowa includes restaurants.

MI: Michigan includes restaurants as a type of retail food establishment and has separate categories for mobile and mobile commissary operations.

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### 18. Contact Name

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